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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,401	03/22/2001	Mark D. Einziger	1932/0H835	3826

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EXAMINER

EVANS, CHARESSE L

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/814,401

Applicant(s)

EINZIGER ET AL.

Examiner

Charesse L. Evans

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-16 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-16 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Action Summary*

Acknowledgement is made of the receipt of applicant's proper response to the restriction requirement, filed, November 18, 2002.

Acknowledgement is made that pursuant to the restriction requirement of June 18, 2002, applicants elected claims 3-16 and 23-25 and the species dialyzate. It is also understood that applicant elects the species dialyzate, so noted in claim 23, as in claim 14.

Claims 3-16 and 23-25 are pending in this action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the term "and/or" renders the claim indefinite and unclear. Correction is requested.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masters et al (US 5,855,871). The elected claims are directed to a slurry comprising spherically shaped and micron sized alkali metal bicarbonate particles in a liquid medium. Masters discloses a composition containing an alkali metal bicarbonate incorporated within a pharmaceutically acceptable dentrifice vehicle suitable for use in the oral cavity. The vehicle

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contains water and other agents (column 2, lines 39-59). The water content is from about 30% to about 60% (column 3, lines 1-2). The alkali metal bicarbonate contained in the disclosed composition is present from about 5 up to 15% by weight (column 3, lines 5-7). The alkali metal bicarbonate present within the composition includes sodium bicarbonate. Sodium bicarbonate is a powder composed of relatively soft particles (column 3, lines 21-24). The size of the sodium bicarbonate particles may vary from course to fine; it is preferred that they be below about 0.4mm in diameter, with a major proportion being below 0.01mm in diameter. The vehicle in which the sodium bicarbonate particles are dispersed is an aqueous vehicle (column 3, lines 20-31). Common ingredients with the disclosed composition include polishing agents, abrasives, surfactants, humectants, pigments, sweeteners, flavor and preservatives (columns 4-5, to line 60).

The prior art does not expressly teach the bulk density, the viscosity or the IR spectra of the bicarbonate particles. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are structurally or functionally

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different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 14-16 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masters et al (US (5,855,871) in view of Itob (US 5,071,558). In light of the discussion above, Itob further discloses a sodium bicarbonate dialysate. The dialytic solution is used to remove uremic waste by means of hemodialysis. The disclosed invention provides a sodium bicarbonate dialysate comprising an electrolyte granule A and an electrolyte granule B, wherein the granule B are granules of sodium bicarbonate primary particles having a particle size of at most 250 micrometers, and the particle size of the secondary particles after granulation is from 0.1 to 10 mm (column 1, lines 8-68). It is preferred that the particle size of the sodium bicarbonate primary particles is at most 100, more preferred at most 50, micrometers (column 2, lines 14-17). The granule B may contain sodium bicarbonate only or may further contain other electrolytes. Other components may optionally be incorporated (column 2, lines 31-33).

When the granules of the referenced invention are to be granulated, powders of the respective components are mixed together with a suitable amount of water. The examples, in columns 6-8, demonstrate a preparation of

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a solution of the granule B, wherein granule B was placed in water and stirred by magnetic stirrer. Additionally, an amount of granule B along with an amount of granule A were dissolved in water at 25 degrees Celsius and then adjusted to over 2 liters (column 6, lines 28-31). When being utilized as a dialytic solution, the bicarbonate dialysate was dissolved in a volume of water (column 9, lines 17-18).

One would be motivated to combine the teachings of the cited references because utilizing granulated or particulate bicarbonate dialysates are useful as waste or debris removal solutions in a variety of compositions. The expected result would be optimization of the easy solubility of bicarbonate dialysates.

### *Conclusion*

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927.

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The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans  
January 22, 2003

  
THOMAS K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600